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B. Document Number: HNF-36361-FP, Revision 0

C. Title: An Approach to Safety Design Basis Documentation Change Control

D. Internet Address:

E. Required Information (MANDATORY)

1. Is document potentially Classified? (•) No ( ) Yes — 4/17/08
   G. W. Ryan
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   ADC Required (Print and Sign) ( ) No ( ) Yes Classified
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I. Reviewers	Yes	Print	Signature	Public Y/N (If N, complete J)
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J. Comments

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A-6001-401 (REV 1)

Thackham, Sherri L

From: Chang, Judy
Sent: Wednesday, May 14, 2008 1:57 PM
To: Thackham, Sherri L
Subject: RE: Clearance of HNF-36361-FP, Revision 0

I have reviewed this paper and approve its release.
H. Judy Chang
FH Legal Services

From: Thackham, Sherri L
Sent: Monday, April 28, 2008 10:59 AM
To: Cherry, Stephen B
Subject: FW: Clearance of HNF-36361-FP, Revision 0

Sherri Thackham
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From: Thackham, Sherri L
Sent: Monday, April 21, 2008 2:19 PM
To: Curtis, Jennifer T; Dunn, Deborah J; Jackson, Mark W
Subject: Clearance of HNF-36361-FP, Revision 0

Attached for your review and approval is the full paper for the May 2008 EFCOG conference. For technical questions please contact Grant Ryan at 376-5114, for editorial questions, please contact me. Thanks!

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From: Dunn, Deborah J
Sent: Monday, April 21, 2008 5:06 PM
To: Thackham, Sherri L
Subject: RE: Clearance of HNF-36361-FP, Revision 0
Attachments: HNF-36361-FP_Rev0-All-DJD.doc

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his document is approved. I am attaching a version with my changes.

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Deborah Jane Dunn
Fluor Hanford Communications
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HNF-36361-FP
Revision 0

An Approach to Safety Design Basis Documentation Change Control

Prepared for the U.S. Department of Energy
Assistant Secretary for Environmental Management

Project Hanford Management Contractor for the
U.S. Department of Energy under Contract DE-AC06-96RL13200

FLUOR®
P.O. Box 1000
Richland, Washington

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AN APPROACH TO SAFETY DESIGN BASIS DOCUMENTATION CHANGE CONTROL

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Abstract

This paper will describe a safety design basis documentation change control process. The process identifies elements that can be used to manage the project/facility configuration during design evolution through the Initiation, Definition, and Execution project phases. The project phases addressed by the process are defined in U.S. Department of Energy (DOE) Order (O) 413.3A, *Program and Project Management for the Acquisition of Capital Assets*, in support of DOE project Critical Decisions (CD). This approach has been developed for application to two Hanford Site projects in their early CD phases and is considered to be a key element of safety and design integration. As described in the work that has been performed, the purpose of change control is to maintain consistency among design requirements, the physical configuration, related facility documentation, and the nuclear safety basis during the evolution of the design. The process developed (1) ensures an appropriate level of rigor is applied at each project phase and (2) is considered to implement the requirements and guidance provided in DOE-STD-1189-2008, *Integration of Safety into the Design Process*. Presentation of this work is expected to benefit others in the DOE Complex that may be implementing DOE-STD-1189-2008 or managing nuclear safety documentation in support of projects in-process.

1.0 INTRODUCTION

This paper describes a safety design basis documentation change control process for managing the project/facility configuration during design evolution through the Initiation, Definition, and Execution project phases defined in U.S. Department of Energy (DOE) Order (O) 413.3A, "Program and Project Management for the Acquisition of Capital Assets," in support of DOE project Critical Decisions (CD). The purpose of change control is to maintain consistency among design requirements, the physical configuration, related facility documentation, and the nuclear safety basis during the evolution of the design. The process ensures an appropriate level of rigor is applied at each project phase.

The change control process implements the guidance provided in DOE-STD-1189-2008, *Integration of Safety into the Design Process*, Section 6.4, "Change Control for Safety Reports as Affected by Safety-in-Design Activities."

2.0 SCOPE

The safety design basis documentation change control process described in this paper may be applied to the design and construction of the following:

- New DOE Hazard Category 1, 2, and 3 nuclear facilities
- Major modifications to DOE Hazard Category 1, 2, and 3 nuclear facilities, as defined by Title 10, *Code of Federal Regulations*, Part 830 (10 CFR 830). A "major modification" means a modification to a DOE nuclear facility that is completed on or after April 9, 2001, that substantially changes the existing safety basis for the facility. Major Modification Evaluation Criteria are included in DOE-STD-1189-2008.
- Other modifications to DOE Hazard Category 1, 2, and 3 nuclear facilities managed under the requirements of DOE O 413.3A.

3.0 REQUIREMENTS AND GUIDANCE

The requirements and guidance contained in DOE-STD-1189-2008 and the DOE orders and standards listed below, primarily were used to develop the safety design basis documentation change control process.

- DOE O 413.3A, *Program and Project Management for the Acquisition of Capital Assets*
- DOE M 413.3-1, *Project Management for the Acquisition of Capital Assets*
- DOE-STD-1073-2003, *Configuration Management.*

Other contractor- and project-specific documents related to the following topical areas also were used or considered:

- Project Execution Plans
- Engineering Management Plans
- Engineering Requirements
- Engineering Configuration Management
- Review and Approval of Technical Documents
- Engineering Document Change
- Design Change Notice Process
- Facility Modification Package Process
- Preliminary Safety Basis Configuration Management Process
- Safety Basis Implementation and Maintenance
- Unreviewed Safety Question Process
- Quality Assurance
- Controlled Software Management.

4.0 CHANGE CONTROL OBJECTIVES

The nuclear safety configuration management actions are tied to the safety documentation that is submitted to DOE for review and approval. The main objectives of the safety design basis change control process for managing the configuration during design evolution are to:

- Identify major process changes or new hazards that could impact potential Design Basis Accidents (DBA)
- Identify potential significant changes to the proposed preventive and mitigative safety structures, systems, and components (SSC) and Technical Safety Requirement (TSR) controls
- Identify significant changes to the proposed overall control strategy (e.g., confinement, fire mitigation)
- Identify significant changes to the functional classification, reliability, or rigor of the design standard for safety SSCs
- Identify significant changes to key assumptions, inputs, or constraints used to develop the design (e.g., Material at Risk [MAR], seismic design) and that could potentially impact the strategy for certain high-cost, safety-related design decisions
- Inform the DOE of potential impacts on major safety decisions and commitments related to cost and schedule, or that could result in costly rework.

5.0 CHANGE CONTROL IMPLEMENTATION

To effectively and efficiently accomplish the change control objectives, existing project and contractor corporate processes are utilized to the extent practical. These methods include the following:

- Formal contractor configuration and change control processes (e.g., technical document review, approval and issue; facility modifications)
- The nuclear safety analysis process
- Integrated Project Teams (IPT)
- Change Control Boards
- Design reviews
- Project-specific Safety Evaluation ("USQ-like") process
- Contractor- and facility-specific Unreviewed Safety Question (USQ) processes
- Tracking of changes to major safety decisions and commitments.

Table 5-1 shows the change control methods that are applied at each CD project phase. Change control rigor is expected to increase as the design evolves from conceptual to final. The change control methods are further described in the following paragraphs.

For engineering, procurement and construction (EPC) projects, the Project Engineering team uses several processes as the change control methods to issue or change the approved design configuration baseline. These methods include the Engineering Document Change (EDC), the Design Change Notice (DCN), and the Facility Modification Package (FMP) processes. The

EDC is used to issue and revise Engineering text documents where control of that document configuration is required for project use. The DCN is used strictly within the EPC to document and control Engineering changes to design media while the corresponding system is controlled by the Project. The FMP is used to issue and control revisions to the existing configuration baseline of facilities in use. Engineering designs and corresponding design media for modifications to existing facilities are contained in FMPs. For example, an FMP would contain the necessary designs for modifying an existing facility to install project-specific SSCs. Subcontractors are required to control their respective design configuration baselines. Where the scope of work is large and design media changes are frequent, projects require that the subcontractor submit (as part of the submittal process) their approved (internally) design changes in the form of Engineering Change Notices (ECN) that are issued and transmitted to the Project as vendor submittals.

The safety analysis process (hazard/accident analyses) performed during all project phases is used as a change control method to identify significant changes to the safety design basis concurrently with the design evolution. Safety analysis provides a key opportunity to influence the design. Each iteration of the safety analysis includes explicit identification of the design information and significant assumptions used to produce the analysis results. Gap analyses are performed for each iteration of the design to identify which portions need reanalysis and the potential impacts on the safety design basis.

Involvement in the IPT is used by Nuclear Safety team members for awareness of the current state of the design with respect to the ongoing safety analysis work being performed, and to facilitate decision making during all project phases.

Some projects may establish a Change Control Board as a change or configuration control method to disposition changes to key configuration baseline documentation, including safety design basis documentation. Members of a contractor-level Change Control Board would typically consist of, as a minimum, the Project Manager, the Technical Services Manager/Chief Engineer, the QA Manager, and the Project Office Manager. Other members such as Nuclear Safety, Facility Operations, Central Engineering, and DOE may be considered. Other projects may use alternate mechanisms to disposition changes to key configuration baseline documentation.

Design reviews conducted during the conceptual and preliminary design phases are used as a change control method to ensure that the views and advice of DOE and contractor personnel can be considered in the evolving design in a timely manner. The Nuclear Safety organization is an active member of the design review teams with approval authority.

A Safety Evaluation ("USQ-like") process established in project-specific procedures is used as the safety design basis change control method upon submittal of the Preliminary Documented Safety Analysis (PDSA) to DOE for review at CD-3. This method reviews changes that could potentially affect the Preliminary Safety Basis (i.e., PDSA) as described in the PDSA. Upon approval of the PDSA, this process includes any potential modifications to the safety design basis identified by DOE in the Safety Evaluation Report (SER). Safety Evaluations are documented on Safety Evaluation forms. See Attachment A for an example Safety Evaluation

form that may be used in conjunction with project-specific guidance. (Note that DOE-STD-1189-2008 does not require a "USQ-like" process to be implemented to satisfy the intent of the Standard.)

The USQ process established in contractor- and facility-specific procedures is used as a change control method upon submittal of the Documented Safety Analysis (DSA) and TSRs to DOE for review at CD-4. This method reviews changes that could potentially affect the Safety Basis (i.e., DSA and TSRs).

As the design evolves and changes to safety decisions and commitments are made, it is intended that the changes primarily be tracked and explained in the Preliminary Safety Design Report (PSDR), PDSA, and in the operational DSA, if necessary. The Safety Evaluation process described above also may serve as an effective tracking method upon submittal of the PDSA to DOE for review at CD-3. It is noted that for projects of significant magnitude and schedule duration it may be necessary to develop and submit to RL for approval (via an updated Safety Evaluation Report) annual (or otherwise periodic) updates of the PDSA to maintain currency with the evolving design.

6.0 REFERENCES

10 CFR 830, "Nuclear Safety Management," *Code of Federal Regulations*, as amended.

DOE M 413.3-1, *Project Management for the Acquisition of Capital Assets*, U.S. Department of Energy, Washington, D.C.

DOE O 413.3A, *Program and Project Management for the Acquisition of Capital Assets*, U.S. Department of Energy, Washington, D.C.

DOE-STD-1073-2003, *Configuration Management*, U.S. Department of Energy, Washington, D.C.

DOE-STD-1189-2008, 2008, *Integration of Safety Into the Design Process*, U.S. Department of Energy, Washington, D.C.

Table 5-1. Change Control for Safety Design Basis Documentation.

CHANGE CONTROL METHOD	CRITICAL DECISION PHASE				
	CD-0 **Approve Mission Need**	**CD-1** **Approve Alternate Selection & Cost Range**	**CD-2** **Approve Performance Baseline**	**CD-3** **Approve Start of Construction**	**CD-4** **Approve Start of Operations or Project Completion**
	Preconceptual Design	**Conceptual Design** **F&R Baseline**	**Preliminary Design** **Design Requirements Baseline**	**Final Design** **Configuration Baseline**	**Acceptance/Completion** **As-Built Configuration Baseline**
	SAFETY DESIGN BASIS DOCUMENTATION				
	Preconceptual HA	**CSDR / CSVR**	**PSDR / PSVR**	**PDSA / SER**	**DSA / TSR / SER**
Change Control Processes EDC / DCN / FMP / ECN	X	X	X	X	X
Safety Analysis Process	X	X	X	X	X
IPT Involvement		X	X	X	X
Change Control Board[1]		X	X	X	X
Design Reviews		X	X	X	
Safety Evaluations				X Upon submittal of PDSA to DOE	
USQ Process					X Upon submittal of DSA/TSR to DOE

[1] A formal Change Control Board may not be established for a project if alternate mechanisms are in place to disposition changes to key configuration baseline documents.

CD = Critical Decision.
CSDR = Conceptual Safety Design Report.
CSVR = Conceptual Safety Validation Report.
DCN = Design Change Notice.
DSA = Documented Safety Analysis.
ECN = Engineering Change Notice.
EDC = Engineering Document Change.
FMP = Facility Modification Package.
HA = hazards analysis.
IPT = Integrated Project Team.
PDSA = Preliminary Documented Safety Analysis.
PSDR = Preliminary Safety Design Report.
PSVR = Preliminary Safety Validation Report.
SER = Safety Evaluation Report.
TSR = Technical Safety Requirement.
USQ = Unreviewed Safety Question.

ATTACHMENT A

SAFETY EVALUATION FORM EXAMPLE

PRELIMINARY SAFETY BASIS CONFIGURATION MANAGEMENT SAFETY EVALUATION FORM
Document Number:
Title: **Applicable Facilities/Systems:** **Scope:** **Description:** **Safety Design Basis Documentation Reviewed:** **Other References:**
1. **Does the new information or engineering change potentially affect the capability of any safety SSC to perform the safety function or meet the associated functional requirements as described in the Preliminary Safety Basis?** **[ ] No [ ] Yes** **Basis:**
2. **Does the new information or engineering change potentially result in a change to the system boundaries or identified support systems for any safety SSC?** **[ ] No [ ] Yes** **Basis:**
3. **Does the new information or engineering change potentially affect parameters used or assumed in safety design basis calculations or in calculations in supporting documents referenced in the Preliminary Safety Basis with respect to consequence or frequency?** **[ ] No [ ] Yes** **Basis:**
4. **Does the new information or engineering change potentially result in a hazardous condition not considered in the Preliminary Safety Basis that has the potential for significant impact to workers, the public, or the environment?** **[ ] No [ ] Yes** **Basis:**

PRELIMINARY SAFETY BASIS CONFIGURATION MANAGEMENT SAFETY EVALUATION FORM	
Document Number:	
5. Does the new information or engineering change potentially result in a change in the function, availability, reliability, or operability of any hazard control designated by the Preliminary Safety Basis such that the mitigation or prevention provided by the hazard control may be degraded? [ ] **No** [ ] **Yes** **Basis:**	
6. Does the new information or engineering change result in a change to the process or equipment descriptions as provided in the Preliminary Safety Basis? [ ] **No** [ ] **Yes** **Basis:**	
Conclusion: [ ] The condition does not require further analysis or any change to the Preliminary Safety Basis. [ ] The change requires further analysis. [ ] The change requires a change to the Preliminary Safety Basis. Safety Basis Change Request Number _____ [ ] The change is beyond the scope of the Preliminary Safety Basis, but requires further analysis or contains information that potentially impacts future Safety Basis development.	
Evaluator #1	**Evaluator #2**
Print Name:	Print Name:
Signature: Date:	Signature: Date:
OTHER REVIEWS (as required)	
Print Name & Sign: Date:	
Print Name & Sign: Date:	
Print Name & Sign: Date:	